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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,360	09/26/2000	Leslie Robert Watson	00P061:RC:SB	8287

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YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER
GORDON, BRIAN R

ART UNIT	PAPER NUMBER
1743	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

VF-18

Office Action Summary	Application No.	Applicant(s)	
	09/555,360	WATSON ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *11-16 and 19-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,17,18,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 11-16 and 19-22 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12. OK

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/AU98/00991, filed on November 27, 1998. ***Information Disclosure Statement***

2. The information disclosure statement filed September 26, 2000 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Copy's of JP 08-334515 is missing. OK

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 35. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. OK

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 36, 47, 67, 102, 182, 184, 198. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

In addition reference numeral 92 labels arrows in figure 6B, however in figure 8A it is unclear what the numeral is indicating.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. The disclosure is objected to because of the following informalities: On page 19, reference numeral 112 indicates both "conveyer belt" and "laminate tape".

On page 20, reference numeral 140 indicates both "spool of tape" and "indexing motor".

On page 15, reference numeral 22 indicates "image analyser" and on page 20 "digital camera".

On page 20, reference numeral 140 indicates both "spool of tape" and "indexing motor".

The specification also contains numerous British/English spellings, American spellings are preferred.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 2, 9-10, 17-18, and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1 and 23-24, it is unclear what is meant by "different types", a characteristic that determines a difference of containers can be numerous things such as height, width, color, contents, volume, etc. It is also unclear what is meant by the term "in turn". The examiner interprets the phrase to mean "sequentially", if this assumption is correct, it is hereby suggest that applicant amend the claim as such to incorporate the above term or any other that suggests the same meaning. It is also unclear how the handling station and identification means are structurally related. It is understood that the handling station comprises the identification means, but there is no indication within the claims how or where the identification means is located within the handling station.

As to claim 1 and 2, it is unclear what is meant by "obtaining one or more characteristics" and "obtaining the identification indicator". The use of such a term implies that the indicator is taken off or from the container. The examiner, hereby

suggests applicant amend the claim to more suggest the invention as described in the specification. The examiner interprets the indicator to be for example a barcode that is read by a bar code scanner/reader. Therefore terms such as detecting, sensing, scanning, or reading are suggested.

As to claim 17, it is unclear what is structural relationship between the hopper and the apparatus and how the apparatus receives the containers from the hopper. Are the containers dropped into, lifted into, etc. from the hopper into the apparatus? ok

As to claim 24, it is unclear if applicant is attempting to claim the "primary container" and "secondary container" as elements of the invention. Considering applicant has described the other elements in relation to these unclaimed elements, the examiner suggests that the containers also be included in the claim. ok

9. Claim 9-10 recite the limitation "one or each secondary container". There is insufficient antecedent basis for this limitation in the claims. ok

10. Claim 10 recites the limitation "the sample information" in 1. There is insufficient antecedent basis for this limitation in the claim. ok

11. Claim 18 recites the limitation "the plunger member" in 5-6. There is insufficient antecedent basis for this limitation in the claim. ok

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

> by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3, 6-10 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Sakazume et al. US, 5,985,215.

14. Sakazume et al. discloses an analyzing apparatus 100 that comprises a rack feeding unit 110 (loading station), a transfer line 130 (distribution station), a discrimination unit 140 (image analyser), the first analyzing unit 150, the second analyzing unit 160, a rack collecting unit 170, and a control part 120 for controlling the above units or components.

Sample racks 20 which are loaded with a plurality of sample containers 10, each of which contains a liquid sample, are set in the rack feeding unit 110 (loading station). The sample rack 20 is a rectangular parallelepiped holder, and it has plural holding holes into which sample containers are inserted. The discrimination unit 140 includes a bar code reader 142 (identification means) for reading a rack bar code label 24 affixed to each sample rack 20 to show information on the sample rack, a bar code reader 144 (identification means) for reading a sample container bar code label 18 (identification

indicator) affixed to each sample container 10 to show information on a sample in the container 10, etc., and a container type discrimination part 146 (identification means) for reading size information (predetermined characteristic) on the length and the width (diameter) of each sample container. The type or shape of each sample container is determined by the discrimination unit 140 and the control part 120. The positions to which the rack bar code label and the sample container bar code label are affixed, are shown in FIG. 3.

If information of an outer diameter or the width (dimensions) of a sample container is described in the bar code label 24 affixed to a rack, the discrimination unit 140 reads the rack number and the information on the outer diameter of sample containers, with a bar code reader 142, and detects the height of each sample container held in the rack, with the container type discrimination part 146 having an optical detector that is shown in FIG. 4. In a memory provided in the control part 120, a reference table stores a relation between each type of a sample container to information of an outer diameter, the length, the presence of a container height adapter, etc., in the type of a sample container. The control part 120 determines the type of a sample container to be discriminated, by comparing the information on an outer diameter of the sample container, which is read on the bar code label 24 by the bar code reader 142, and the information on the length of the sample container, with the information described in the reference table.

The information on the outer diameters at the predetermined detection levels, as to each sample container, the outer diameters being detected by the container type

discrimination part 146, is sent to the control part 120. A memory in the control part 120 stores relations between the information of the outer diameters at the predetermined detection levels, and the time intervals of "1" or "0" level in output signals at the corresponding detection levels from the light reception part 146b, as to each type of a container, as a table in advance.

By examining correspondence between the detected information and the stored information, as to the sample container to be discriminated, the control part 120 (processing means) can further reconfirm the type of the discriminated sample container.

Furthermore, the control part 120 (processing means) determines which unit of the first and second analyzing units includes a pipetting mechanism suitable for the discriminated type of each sample container, and transfers the rack 20 holding the sample container to the analyzing unit to be determined as suitable, so that a sample in the sample container is pipetted by the suitable pipetting mechanism, by moving the transfer line 130. For example, as to the test tubes 16a and 16c shown in FIG. 5A, when each of these containers is transferred to the first analyzing unit, the sample in the container is pipetted by the sample pipetting mechanism 152 at the sample pipetting position 154. On the other hand, as to the test tubes 16b and 16d, and the small quantity measurement container 14 shown in FIG. 5A, when each of these containers is transferred to the second analyzing unit, the sample in the container is pipetted by the sample pipetting mechanism 162 at the sample pipetting position 164.

15. Claims 1-2, 6-10, 17-18, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Kirk et al. US 5,798,035.

Kirk et al. discloses a method and system for biological assays in which a plurality of o reaction vessels have bar codes (identifying indicia) that are "electronically readable" (optically readable) to identify each vessel.

The system allows for the random mixing and separating of the reaction vessels after one or more reaction steps, which may be performed when creating combinatorial libraries. For example, a group of reaction vessels may be removed from several reaction chambers, mixed and randomly separated into two or more groups for delivery to different reaction chambers for different subsequent reactions. After these reactions, additional random mixing and separating, as well as additional reactions may occur. Data relating to the reactions, e.g., reagents and reaction conditions, may be reflected by the reaction vessels' identifying indicia, e.g., bar codes. These identifying indicia may be read, e.g., electronically, immediately prior to or after a reaction step has occurred. Such indicia, along with the specific reaction step information corresponding thereto, may be recorded and stored, e.g., in a database (storage device). The reaction history of each individual reaction vessel can therefore be tracked, and the chemical recipe determined for the compounds synthesized, respectively, within each vessel.

In the "pre-selected recipe method," (predetermined characteristic) the reaction vessels may be deliberately sorted (determining the placement of the containers) into reaction chambers to undergo specific reactions represented by the indicia.

An extrusion means (distribution station) such as a tool or other device may be used to remove the reaction vessels from the reaction chambers (loading station). The extrusion means may be adapted for insertion into the reaction chambers and for contact with individual reaction vessels therein. A sorting means receives the reaction vessels extruded from the reaction chambers and sorts the reaction vessels into one or more groups, to be determined based on the particular reaction or reactions to be performed within the reaction vessel. The sorting means may include a reader adapted to read identifying indicia, such as a bar code, on the reaction vessel. The sorting means may also include means for removing the extruded reaction vessels from a hopper which collects the reaction vessels after extrusion from the reaction chamber. A ramp or belt may be used to move the extruded reaction vessels to a vessel director disposed to load one or more reaction vessels into a vessel loading device. The vessel loading device is adapted to receive a reaction chamber and guide array therein and is moveable along a first and second axis to allow insertion of any reaction vessel in a particular location within the reaction chamber (loading station). A means for receiving one or more extruded reaction vessels from the sorting means, such as a robotic pipettor adapted to a vessel transfer array, may be used to communicate with the reaction vessels and deposit synthesized compounds eluted therefrom into a plurality of wells of, e.g., a 96-well plate, or onto a lawn bioassay plate (determining if aspiration is required).

FIG. 5 depicts a schematic of a system which shows how the compounds in the reaction vessels 1 are released and sampled into standard 96-well microtiter plates

after combinatorial synthesis within the reaction vessels 1 is complete. Reaction vessels 1 are loaded into a hopper 15 using the extrusion tool 13 and plunger 14. The reaction vessels 1 may be removed from the hopper via feed mechanism 16 and loaded in order of feeding onto an alignment fixture 27 (container alignment means), which may be designed specifically for use with the 96-well plate format, using a short ramp 28 or conveyor belt (not shown) and by mechanically moving the alignment fixture 27, preferably in increments, under the short ramp 28. A bar-code reader 18 reads the codes on the reaction vessels 1 as they roll down the ramp 28 and a computer (not shown), interfaced with the bar code reader, tracks the vessels as they are loaded onto each alignment fixture 27. One of ordinary skill in the art can readily utilize software to determine which vessels 1 are loaded in what order onto each alignment fixture 27 for screening. Each alignment fixture 27 may be rotated so that the reaction vessels 1 are vertically oriented.

16. Claims 1-2, 6-8, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al. US 5,948,360.

Rao et al. disclose a modular vial autosampler has a storage area for vials containing samples to be analyzed and at least one modular sampling station. A vial transfer mechanism includes an arm having a gripper that lifts a sample vial from the storage section, and the arm moves it to a station for identification and then to a sampling station, and under central control activates the sampling station for obtaining a sample for analysis. The vial transfer mechanism gripper is movable in X, Y, and Z directions to capture and move a selected vial and includes an alignment guide for the vials.

The vial handling device in the sampling station moves a vial having a specimen therein from a loading site where it is placed by the gripper head, to a sampling site, and includes a carrier adapted to hold the vial, an elevator coupled to the carrier, and a mechanism to translate the carrier laterally as the vial is transported from the loading site to the sampling site.

The device 10 includes a vial equilibration station 16 that has an upper surface on which a "home" position calibration pad 17 is formed or mounted. The pad 17 is centered on the base unit and, as will be explained, is used for calibrating the position control system for the vial transporter 28. The equilibration station 16 comprises four ports 56a, 56b, 56c, 56d in the base unit 12 where vials can be placed for a programmable period of time to warm up (or cool down) to the ambient room temperature. Port 56c also functions as vial identification station 18. An outer side wall of each vial can have a sticker bearing a unique bar code pattern for vial identification. An optical bar code reader assembly 58, available commercially and well known, is disposed in base unit 12 and views the side wall of the vial in port 56c through a vertical slot 60 (partially visible in FIG. 1) in the wall surrounding port 56c. A rotatable disk 62 is provided at the bottom of port 56c and is coupled to a stepper motor 64 controlled by a microprocessor based central control circuit 66. When stepper motor 64 rotates disk 62 (controller which controls rotatable container), the vial resting on the disk 62 rotates until the bar code pattern on the vial wall is detected by reader assembly 58 through slot 60. Central control circuit 66 then turns off stepper motor 64. The bar code reader keeps track of the vials and samples, throughout the

test and the controls can insure the results are attached to the proper sample by the bar code use. The bar code reader forms an input to control module 66 and control module can be used to correlate analysis with the appropriate vial.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakazume et al. US, 5,985,215 as applied to claims 1-3, 6-10, and 23 above, and further in view of Rao et al. US 5,948,360.

Sakazume et al. do not disclose that the device has a rotatable container receiving means.

Rao et al. discloses an automated sampling device that comprises an optical bar code reader assembly 58, available commercially and well known, is disposed in base unit 12 and views the side wall of the vial in port 56c through a vertical slot 60 (partially visible in FIG. 1) in the wall surrounding port 56c. A rotatable disk 62 is provided at the bottom of port 56c and is coupled to a stepper motor 64 controlled by a microprocessor based central control circuit 66. When stepper motor 64 rotates disk 62 (controller which controls rotatable container), the vial resting on the disk 62 rotates until the bar code pattern on the vial wall is detected by reader assembly 58 through slot 60. Central control circuit 66 then turns off stepper motor 64. The bar code reader keeps track of the vials and samples, throughout the test and the controls can insure the results are attached to the proper sample by the bar code use. The bar code reader forms an input to control module 66 and control module can be used to correlate analysis with the appropriate vial.

It would have been obvious one of ordinary skill in the art at the time of the invention to modify the device of Sakazume to employ the rotating disk of Rao to allow for the proper alignment of the vial in order to read the bar code.

Allowable Subject Matter

21. Claim 24 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

22. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or fairly suggest the device as claimed by applicant: A pathology sample distribution system having a plurality of containers of different types and the containers each containing a sample of pathology analysis, the system comprising: primary container identification means; the identification means including a bar code scanner to scan bar coded labels and an image analyser to analyse one or more characteristics of the container and/or the sample therein; primary container cap removal and replacement means; hopper means having container alignment means for delivering secondary containers each with a closed end and an open end in a vertical position and with the open ends in position to receive samples; sample aspiration and/or dispensing means for aspirating and/or dispensing volumetrically proportions of the samples from the primary container; blockage detection means for detecting blockage of flow in the sample aspiration means; secondary container sealing means; secondary container labeling means; secondary container storage means; container conveyance means; where in operation each primary

container containing a sample is presented to the identification means and the container is accepted or rejected according to given criteria; the identification means being arranged to reject a container when it flails to detect the given criteria and thereby indicating the presence of an error condition, when the given criteria are detected the cap of the primary container is removed and aliquots of the sample aspirated by the sample aspiration and/or dispensing means are dispensed to the secondary container or containers which are then sealed and labeled and placed in the storage means; and whereby the conveyance of the primary containers and secondary containers between operational steps is via the container conveyance means and the whole process is coordinated and controlled by a computerized laboratory information management system.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ricci et al., Williams et al., Kodama et al., Barber et al., Moran, Marker et al., Laska et al., Iwasaki et al., Kanamori et al., Torchia et al., Berndt, Markin, Aota et al., Goodman et al., Seaton et al, Rao et al. (US 6143573), Koakutsu et al., Pang et al., Kirk et al. (RE37,194) and Friedlander et al., disclose automated devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for

the organization where this application or proceeding is assigned are (703) 305-7719 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
June 27, 2002

Jill Warden
Supervisory Patent Examiner
Technology Center 1700